

H.R. 2356
Prescription Drug Comparative Effectiveness Act of 2003

Summary

- The Prescription Drug Comparative Effectiveness Act of 2003 requires the National Institutes of Health (NIH) to conduct research, and the Agency for Healthcare Research and Quality (AHRQ) to conduct studies, on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of expenditures or use by individuals in federally funded health programs.
 - Currently, drug companies promote their drugs as safer or more effective than competing drugs, but this promotion is too often based on poorly-designed studies or other questionable sources of information. The FDA is responsible for determining safety and effectiveness of prescription drugs (does the drug treat the condition its label says it treats), but there is no government entity responsible for examining the comparative effectiveness of prescription drugs (e.g., is drug A more effective at treating a particular condition than drug B). FDA judges the effectiveness of drugs compared to a placebo but does not ordinarily make judgments about the comparative effectiveness of drugs for the same indication, nor does it take into account relative costs.
- The Act directs AHRQ to submit an annual report to Congress, NIH, CMS, and other federal health care agencies delineating their findings. The report would be publicly available, including posting on the NIH internet site.
- The Act authorizes \$50 million for NIH and \$25 million for AHRQ in FY04 to carry out these directives.
- The goal of the legislation is to establish an independent source of evidenced-based research on drug comparative effectiveness and cost-effectiveness. NIH and AHRQ would develop an extended source of comparative information on drugs, accessible to clinicians, private physicians, and the public.